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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/084,615

02/28/2002

Motoo Yamasaki

249-159

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23117

7590

04/20/2005

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EXAMINER

BORIN, MICHAEL L

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/084,615

Applicant(s)

YAMASAKI ET AL.

Examiner

Michael Borin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 24 and 34-44 is/are pending in the application.
- 4a) Of the above claim(s) 35-37 and 40-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24, 34, 37 and 38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 01/2005
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Amendment filed 01/24/2005 is acknowledged. Claims 1-23, 25-33 are canceled. Claims 34-44 are added. Claim 34 is rewritten claim 24(b); claims 35-43 are rewritten original claims 25-33, respectively. Claims 35-37, 40-43 remain withdrawn from consideration as drawn to non-elected species. Claims 24,34,37,38 are under examination to the extent they are drawn to elected species – hG-CSF of SEQ ID No. 1 modified at amino group with polyethyleneglycol derivative. are under examination.

***Claim Rejections - 35 USC § 102 and 103.***

2. Claims 24,34,37,38 are rejected under 35 U.S.C. 102(e) as anticipated by Ishikawa et al. (US 5,824,778). The rejection is maintained for reasons of record set forth for claims 24,28,29 and further in view of the following.

Applicant argues that Ishikawa et al. does not teach increase of platelet count. The reference teaches treatment of patients with decreased platelet counts by administering hG-CSF of instant SEQ ID No. 1 and chemically modified by using polyethylene glycol. Under the principles of inherency, if a prior art method, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art. When the prior art method is the same as a method described in the specification, it can be assumed the method will inherently perform the claimed process. See MPEP 2112.02

3. Claims 24,34,37,38 are rejected under 35 U.S.C. 103(a) as obvious over Tanikawa or Koike et al, or Washizuka et al, in view of Ono et al (US Patent 5,342,940)

or Ishikawa et al. (US 5,824,778). The rejection is maintained for reasons of record set forth for claims 24,28,29 and further in view of the following.

With respect to Tanikawa reference, applicant argues that Yamasaki Declaration (copy attached to response of 05/20/2004) demonstrates unexpected effect of increasing platelet count. Example 2 to which Declaration refers addresses use of one particular substitute derivative of SEQ ID No. 1, namely compound "k" of Table 1. Further, this substitute derivative is further modified by polyalkyleneglycol at unspecified locations – note that Example 2 describes obtaining a mixture of mono-, di-, and tri-substituted derivatives modified at unspecified locations (which may be not only -NH<sub>2</sub>, but also -OH, or -COOH, or -SH groups as well). Thus, at best the showing of "unexpected effect"<sup>1</sup> is limited to a particular derivative of not fully known structure and does not commensurate with the scope of the claims. With respect to elected species in particular, the Declaration does not provide any evidence of unexpected effect.

With respect to the references of Koike et al. and Washizuka et al, applicant's analysis of the references is single-sided. Applicant argues that Koike discloses on p. 291, lines 10-14 that hG-CSF does not increase platelet count. The purpose of publication, however, is to demonstrate that G-CSF causes increase in platelet count – see Title. Further, both experimental data (case 1, p. 290, line 7), and discussion of prior art p. 289, first paragraph, demonstrate that G-CSF causes a rise in platelet count.

Applicant further argues that Washizuka et al demonstrates decrease, rather than increase in platelet count. In pointing at effect of G-CSF several months after beginning of administration (Fig. 1, bottom curve, after year 1990) applicant deliberately ignores showing of increase in platelet count caused by administration of G-CSF – see

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<sup>1</sup> That such effect is expected from prior art is discussed below.

beginning of the same curve. Further, the latter is the conclusion arrived at by the authors of the reference – see p. 153, title, end of first paragraph, third paragraph, and last full paragraph.

Thus, Examiner maintains that it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to be motivated to modify hG-CSF with a polyethylene glycol derivative to improve its pharmacological properties and to use thus modified hG-CSF to increase platelet count in patients in need thereof, for example patients suffering from decreased platelet count.

#### ***Information Disclosure Statement***

4. Applicant requests consideration of Japanese patent references listed in IDS filed 12/07/2002. Applicant now submitted International Search Report of the parent pct application issued by Japanese Patent Office. Therefore, these references are considered, in accordance with requirements of MPEP 609.III A(3):

Where the information listed is not in the English language, but was cited in a search report or other action by a foreign patent office in a counterpart foreign application, the requirement for a concise explanation of relevance can be satisfied by submitting an English-language version of the search report or action which indicates the degree of relevance found by the foreign office. This may be an explanation of which portion of the reference is particularly relevant, to which claims it applies, or merely an "X", "Y", or "A" indication on a search report.

#### ***Conclusion.***

5. No claims are allowed

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Borin, Ph.D.  
Primary Examiner  
Art Unit 1631

mlb